

## TOTAL COSTS OF THE PROCESS FOR THE REVIEW OF HUMAN DRUG APPLICATIONS

Table 7 shows the costs for the review of human drug applications during the past two fiscal years by FDA organizational component. It depicts the full cost of the process for the review of human drug applications paid from appropriations and user fees. The table displays data for the Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), Office of Regulatory Affairs (ORA) and FDA Headquarters (HQ).

**TABLE 7: PROCESS FOR THE REVIEW OF HUMAN DRUG APPLICATIONS – TOTAL COST AS OF SEPTEMBER 30, 2012 AND SEPTEMBER 30, 2013**

FDA COMPONENT	FY 2012	FY 2013
CDER	\$714,461,517	\$661,662,397
CBER	\$201,589,189	\$191,204,309
ORA	\$37,186,485	\$31,508,236
HQ	\$79,182,027	\$81,794,065
<b>TOTAL PROCESS COSTS</b>	<b>\$1,032,419,218</b>	<b>\$966,169,007</b>
Obligations from Appropriations	\$395,490,417	\$299,267,407
Obligations from Prescription Drug User Fees	\$636,928,801	\$666,901,600

Of the total of \$966.169.007 obligated in FY 2013 for the process for the review of human drug applications as defined in PDUFA, about 69 percent came from PDUFA user fees and about 31 percent came from appropriations.

In FY 2013, the total costs for the process for the review of human drug applications decreased by about 6 percent from the cost for the process in FY 2012, mostly due to the impact of funding uncertainty in the first six months of the fiscal year, and the impact of the sequester.

The next three tables are new to the financial report this year, and are an attempt to provide some additional trend analysis in response to suggestions from FDA stakeholders.

Table 8 shows the total spending on the drug review process by major FDA component over the past ten years. The percentage spent in the various FDA components has remained essentially stable over time.

**TABLE 8: PROCESS FOR THE REVIEW OF HUMAN DRUG APPLICATIONS – TOTAL SPENDING BY MAJOR ORGANIZATIONAL COMPONENT FROM FY 2004**

FY	Total Spent	Spent by CDER	CDER %	Spent by CBER	CBER %	Spent by ORA	ORA %	Spent by HQ	HQ %
2004	\$436,856,536	\$293,991,408	67	\$91,905,443	21	\$19,646,087	5	\$31,313,598	7
2005	\$480,952,183	\$332,515,484	69	\$94,765,165	20	\$22,590,258	5	\$31,081,277	6
2006	\$524,303,323	\$363,449,183	69	\$103,800,146	20	\$23,260,052	5	\$33,793,942	6
2007	\$575,005,992	\$385,939,977	67	\$122,871,873	21	\$25,860,072	5	\$40,334,070	7
2008	\$713,900,390	\$493,748,819	69	\$145,080,623	20	\$27,811,039	4	\$47,259,909	7
2009	\$855,426,294	\$585,414,578	68	\$170,363,705	20	\$36,509,080	4	\$63,138,931	8
2010	\$931,845,581	\$640,509,784	69	\$176,353,112	19	\$34,968,204	4	\$80,014,481	8
2011	\$1,025,621,707	\$719,677,685	70	\$199,895,537	20	\$37,783,238	4	\$68,265,247	6
2012	\$1,032,419,218	\$714,461,517	69	\$201,589,189	20	\$37,186,485	4	\$79,182,027	7
2013	\$966,169,007	\$661,662,397	68	\$191,204,309	20	\$31,508,236	3	\$81,794,065	9

Numbers may not add due to rounding

FDA strives to maintain a low overhead cost for the process for the review of human drug applications. Agency general and administrative costs were approximately 8.5 percent of total spending in FY 2013. The development of the costs associated with the process for the review of human drug applications is described in more detail in Appendix D.

Table 9 provides historical data on the FTEs used in the process for the review of human drug applications by major FDA component.

**TABLE 9: PROCESS FOR THE REVIEW OF HUMAN DRUG APPLICATIONS – TOTAL FTE USED AS OF SEPTEMBER 30, OF EACH FISCAL YEAR**

Component/FY	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
CDER	1,740	1,695	1,811	1,809	1,912	2,344	2,552	2,666	2,636	2,450
CBER	499	488	501	574	610	658	710	722	740	748
ORA	150	148	151	163	165	217	192	198	183	166
HQ	219	215	231	191	238	307	306	291	295	290
<b>Total</b>	<b>2,608</b>	<b>2,546</b>	<b>2,691</b>	<b>2,738</b>	<b>2,925</b>	<b>3,526</b>	<b>3,760</b>	<b>3,877</b>	<b>3,854</b>	<b>3,655</b>

Numbers may not add due to rounding

Table 10 provides the total amount spent on the drug review process for the last 10 years, and the amount and percent of that total that is derived from fees and from new budget authority.

**TABLE 10: PROCESS FOR THE REVIEW OF HUMAN DRUG APPLICATIONS – TOTAL SPENDING FROM FEES AND BUDGET AUTHORITY AS OF SEPTEMBER 30, OF EACH FISCAL YEAR**

Fiscal Year	Total Spent	Spent from Budget Authority	Budget Authority Percent	Spent from PDUFA Fees	PDUFA Fee Percent
2004	\$436,856,536	\$204,775,036	47%	\$232,081,500	53%
2005	\$480,952,183	\$211,518,383	44%	\$269,433,800	56%
2006	\$524,303,323	\$218,659,186	42%	\$305,644,137	58%
2007	\$575,005,992	\$254,576,372	44%	\$320,429,620	56%
2008	\$713,900,390	\$263,113,555	37%	\$450,786,835	63%
2009	\$855,426,294	\$343,374,894	40%	\$512,051,400	60%
2010	\$931,845,581	\$358,587,181	38%	\$573,258,400	62%
2011	\$1,025,621,707	\$397,795,307	39%	\$627,826,400	61%
2012	\$1,032,419,218	\$395,490,417	38%	\$636,928,801	62%
2013	\$966,169,007	\$299,267,407	31%	\$666,901,600	69%